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## **Administrative Rules for the Instructions and Labels of Medical Devices**

### Article 1

The administrative rules are formulated in accordance with the Regulations on the Supervision and Administration of Medical Devices, with a view to standardizing the instructions and labels of medical devices, to guarantee the safe usage of medical devices.

### Article 2

All the medical devices sold and used within the territory of the People's Republic of China shall be subject to attach instructions and labels in accordance with these administrative rules.

### Article 3

The instructions of medical device refer to the technical documents which are made by the registration applicant or record applicant, and provided to users with the product. It shall cover the basic information of safety and effectiveness for guiding the correct installation, debugging, operation, use, repair and maintenance.

The labels of medical device refer to the text, graphics or symbols which are attached on medical device itself or its packaging to be used for identifying products features, safety warnings and other information.

### Article 4

The content of the instructions and labels shall be scientific, true, complete, accurate, and consistent with the product features.

The content of the instructions and labels shall be consistent with the relevant content of registration or record.

The content of the labels shall be consistent with the relevant content of the instructions.

### Article 5

The descriptions of disease names, professional terms, diagnostic and therapeutic processes and results in the instructions and labels shall adopt the professional terms which are published or standardized nationally, and the metrological units shall comply with the relative national standards.

### Article 6

Symbols or marking colors in the instructions and labels of medical devices shall comply with the relative national standards. If there is no relevant standard, the symbols and marking colors shall be described in the instructions and labels.

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#### Article 7

The instruction shall be attached in the minimum sales unit of medical device.

The user shall use the medical device according to its instruction.

#### Article 8

The name of medical device product shall be the generic name. Generic name should comply with the naming rules for medical devices formulated by the State Food and Drug administration. The name of Class II and Class III medical device products should be consistent with the name of the product in Registration Certificate.

Product name of product shall be clearly marked in prominent position of the instructions and labels.

#### Article 9

The instructions and labels of medical device shall be in Chinese and the use of Chinese shall meet the national common language specification. Other languages may be attached to the instructions and labels, but the Chinese statement shall prevail.

#### Article 10

The instructions of medical device shall include the following information generally:

1. Product name, model and specification;
2. Name, resident, contacts and after-sale service institute of the registration applicant or the record applicant. The imported medical device shall also specify the name, resident, contacts of the agent;
3. Name, resident, manufacturing address, contacts, number of the manufacture certificate or the manufacture record certificate. For commissioned manufacture, resident, manufacturing address, number of the manufacture certificate or the manufacture record certificate of the commissioned party shall also be included;
4. The number of the manufacture certificate or the manufacture record certificate of medical devices;
5. The number of product technical requirements;
6. Product performance, main structural composition or components, scope of application;
7. Contraindications, precautions, warnings and matters needing attention;
8. Instructions or graphics for installing and use; medical device used by individual consumers shall also have special instructions for safe usage;
9. Product repair and maintenance methods; unique conditions and methods for storage and transportation;
10. Date of manufacture and shelf-life; or date of manufacture and expiration date;
11. Parts List, including explanations for replacement cycle and replacement method of parts, accessories, consumables and so on;
12. Explanations for graphics, symbols and abbreviations used in labels of medical devices;

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13. Compilation or revision date of the instructions;
  14. Other contents shall be included.

#### Article 11

Precautions, warnings and suggestive descriptions in the instructions of medical devices mainly include:

1. Objectives of product use;
2. Potential safety hazards and usage restriction;
3. Protective measures, emergency measures and corrective measures shall be taken for operators and users when accidents occurred in properly using products;
4. Necessary monitoring, evaluation and control methods;
5. Single-use products shall be marked "single use" words or symbols; sterile products shall indicate sterilization method and processing methods when sterilization package is broken; products need to be disinfected or sterilized before use shall be specified with methods of disinfection or sterilization.
6. When products need to be installed or used in conjunction with other medical devices, it shall indicate the requirements, operation methods and precautions for medical devices used in conjunction;
7. Mutual interferences and possible risks may produce with other products during the use process;
8. Adverse event may be brought during product using; product composition contains ingredients or excipients that may introduce side effects;
9. Precautions for disposal of medical device wastes; for products need to be disposed after use, corresponding processing methods shall be provided
10. Other descriptions need to be noticed by operators and users according to product characteristics.

#### Article 12

Processing procedures of reuse for the reusable devices shall be specified in the instructions which are including cleaning, disinfecting, packaging and sterilizing methods, time limits or others.

#### Article 13

The labels of medical device shall include the following information generally:

1. Product name, model and specification;
2. Name, resident and contacts of the registration applicant or the record applicant. The imported medical device shall also specify the name, resident, contacts of the agent;
3. The number of the manufacture certificate or the manufacture record certificate of medical devices;
4. Name, resident, manufacturing address, contacts, number of the manufacture certificate or

the manufacture record certificate. For commissioned manufacture, resident, manufacturing address, number of the manufacture certificate or the manufacture record certificate of the commissioned party shall also be included;

5. Date of manufacture and shelf-life; or date of manufacture and expiration date;
6. Power supply connection conditions and input power;
7. Graphics, symbols and other relevant information required by product's characteristics;
8. Necessary precautions and warnings;
9. Special storage and operation conditions or explanations.
10. For medical device that may be hazard or had negative effects to the environment, its label shall contain warning symbol or warning message in Chinese
11. For medical device producing radiation, its label shall contain warning symbol or warning message in Chinese

For those descriptions are limited by position or size of labeling of medical devices, product name, models and specifications, date of manufacture and shelf-life or date of manufacture and expiration date of the product shall at least be specified, and "refer to IFU for details" shall also be specified in labeling.

#### Article 14

Following contents are forbidden in the instructions and labels:

1. Functional or effective asserts or assurances , such as "The best therapeutic effectiveness" "guarantee to cure" "cure all diseases" "cure once and for all" "with immediate effect" or "nontoxic and non-side effect at all", etc. ;
2. Absolute words or expression, such as "the highest technology", "the most scientific", "the most advanced", "the best", etc. ;
3. Descriptions of cure rate or effective rate;
4. Comparisons of effectiveness and safety with products of other enterprises.
5. Promissory descriptions like "secured by insurance company" or "refund for no effect";
6. Using name or image of any entity or person as demonstration or recommendation;
7. Misleading description to make people feel that they are suffering from some diseases, or make people misunderstand that they will suffer from some diseases or the diseases will be aggravated if not using the medical devices, and other false, exaggerated and misleading content;
8. Others forbidden by laws or regulations.

#### Article 15

The instructions of medical device shall be submitted to the food and drug regulatory authority for review or record when the registration applicant or the record applicant applies for medical device registration or record. The submitted instructions shall be consistent with other registration or record documents.

#### Article 16

The contents of medical device instructions which are reviewed and registered by the food and drug regulatory authority shall not be altered without authorization.

In case of any change registration for registered medical device, the applicant shall revise the instructions and labels according to the change document after obtaining the change document by itself.

In case of any change to other contents of the instructions, the review and approval department for medical device registration shall be informed in written and the relevant documents such as the comparison statement on the change of the instructions shall be submitted. The change of the instructions will be effective if there is no disagreement notice sent by the review and approval department for medical device registration within 20 workdays after receiving the written notice.

#### Article 17

In case of any change to the content of record information form, product technical requirement, instruction or others of medical device filed, the record applicant shall revise the relevant content of instructions and labels by itself.

#### Article 18

If instructions and labels of medical devices are not in compliance with the Provisions, a punishment shall be imposed by the food and drug regulatory authority at the county level and above in accordance with the provisions in Article 67 of the Regulations for the Supervision and Administration of Medical Devices.

#### Article 19

These administrative rules shall come into force as of October 1, 2014, and also abolish the administrative rules for the instructions, labels, and packaging marking of medical device issued on July 8, 2004 (the former Order No.10 of State Food and Drug Administration).